

REMARKS

Formal Matters

Claims 18 and 19 remain pending in this application. Applicants have amended claim 19 to more particularly point out the claimed invention.

The Examiner has objected to the specification as containing improperly marked trademarks. Applicants have amended the specification to mark the trademarks as such and to provide the corresponding generic terminology. No new matter has been added by way of this amendment.

Definiteness Rejection Under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claim 19 as allegedly indefinite for improperly containing trademarks. Applicants have replaced the tradenames with the generic names. No new matter has been added by this amendment and Applicants ask that the Examiner withdraw this rejection.

The Examiner has also rejected claim 19 as the term "hardly soluble" is allegedly unclear. Applicants have deleted the objected-to term from claim 19 and ask that the Examiner withdraw this rejection.

Written Description Rejection Under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 18 and 19 as allegedly lacking written description support in the specification. The Examiner has made this rejection because the Examiner believes that the structure of the claimed growth factor peptide has not been described. The Examiner asserts that, while the specification provides some

examples of growth factor peptides, the claim allegedly only provides functional limitations. In responding to this rejection, Applicants will address claims 18 and 19, separately.

Claim 18 is a product-by-process claim. In other words, it claims peptides obtained by a specific method. Thus, the claimed peptides may be obtained by following the process steps recited in the claims. Applicants are not describing the properties of the peptide of claim 18 functionally, but are instead describing the specific process steps that must be taken in order to isolate it.

The Examiner's citations of *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997) is not applicable to claim 18. This case explores the application of the written description requirement to composition claims. *Id.* The two cases upon which the *Lilly* decision relied are, however, relevant to claim 18, and both negate the Examiner's rejection.

The first case discusses the related topic of conception and holds that:

[c]onception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its **method of preparation**, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property.

Amgen Inc. v. Chugai Pharmaceutical Co., 18 U.S.P.Q.2d 1016, 1021 (Fed. Cir. 1991) (emphasis added). Methods of preparing a composition, such as defined in product-by-process claim 18, are sufficient for written description and conception purposes. The Federal Circuit groups methods of preparation with structure and physical properties, but distinguishes them from biological or functional descriptions of proteins.

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This interpretation of product-by-process claims is further discussed in *Fiers v.*

Revel, which holds:

We recognized that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute a conception of the substance claimed as a process. Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties.

Fiers v. Revel, 25 U.S.P.Q.2d 1601, 1605 (Fed. Cir. 1993). Thus, under these two pre-*Lilly* decisions product-by-process claims do not need any further recitation of structure, name, formula, or definitive chemical or physical properties. Indeed, these cases acknowledge that process limitations are not improper functional definitions. Thus, claim 18 does find adequate written description support in the specification.

Claim 19 is directed to a plant growth factor peptide. This claim, contrary to the Examiner's suggestion, expressly sets forth physical properties of the claimed peptides. Indeed, the law on which the Examiner relies allows inventors to describe a chemical or biological invention "by structure, formula, chemical name, or physical properties." See *Lilly*, at 1566, 43 U.S.P.Q.2d. at 1404. The only impermissible mode of defining a chemical or biological invention is by merely providing a functional definition. A functional definition is only an indication of what a peptide does (such as in this case, promoting growth). *Id.* at 1568, 43 U.S.P.Q.2d at 1406. Applicants have not defined the embodiment of claim 19 functionally, such as by only describing that the peptide is a

plant growth factor. Instead, claim 19 expressly recites a number of physical properties, as permitted by law. While the claim does not recite a chemical formula or amino acid structure, the law equates physical properties with structural formulas as ways to satisfy the written description requirement.

Solubility in water is a well recognized physical property of a composition and a known way to differentiate compositions. The acidic nature of a peptide is also a physical property and that this can easily be tested with a pH meter or litmus paper, and does not require consideration of whether the peptide contains specific acidic residues at particular sequence positions, as the Examiner suggests. Lastly, the polar nature of this peptide and the fact that it is adsorbed to DEAE but not CM ion exchange resins also provides information on the physical properties of the claimed peptides.

Finally, the specification does disclose a sufficient number of peptide growth factor species. Applicants need not describe all species that a claim encompasses to fulfill the written description requirement. *Utter v. Hiraga* 845 F.2d 993, 998, 6 U.S.P.Q.2d 1709, 1714 (Fed. Cir. 1988).

Therefore, Applicants request that the Examiner withdraw this rejection.

Obviousness-Type Double Patenting Rejection

The Examiner has rejected claim 18 and 19 as unpatentable under the judicially-created doctrine of obviousness-type double patenting as unpatentable over claims 1-14 of U.S. Patent 6,004,906. Applicants enclose a terminal disclaimer to overcome this rejection.

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Conclusion

Should the Examiner wish to discuss the merits of this case, Applicants invite the Examiner to telephone the undersigned representative at 202-408-4086. If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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